UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Date: June 17, 2013

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No. 43917-7

Product Name: Spira Area Mosquito Repellent

DP Barcode: 409004

PC Code: 004005 d-Allethrin

From: Shirley Keel, Biologist

Risk Management and Implementation Branch V

Pesticide Re-evaluation Division (7508P)

To: Molly Clayton, CRM

Risk Management and Implementation Branch V

Pesticide Re-evaluation Division (7508P)

Applicant: Zobele Holding S.p.A.

c/o Paul A. Keane & Associates

P.O. Box 65436 Tucson, AZ 85728

FORMULATION FROM LABEL:

		<u>% by wt.</u>
Active Ingredient(s):		
d-Allethrin		. 21.97
Other Ingredient(s):	•••••	. 78.03
	Total	100.00

Background Information:

In the eight-month response to the Allethrin RED, the registrant has submitted the following acute toxicity studies—MRIDs 487877-01 thru -04 (870-1100, -1200, -1300, & -2400 respectively), 488643-01 (870-2500) and 487877-06 (870-2600) to support the reregistration of product EPA Reg. No. 43917-7. MRID No. 487877-01 & -03 are waiver requests for the acute oral and acute inhalation toxicity studies. The subject product is an impregnated material. It was impossible to obtain sufficient test material to conduct the tests to accurately determine acute oral or inhalation toxicity. The waiver requests for the data requirements of Guidelines 870-1100 and -1300 are granted. The studies reported in MRID Nos. 488643-01, 487877-02, -04 and -06 were conducted by Stillmeadow, Inc. The test material used in these studies was the subject product.

Findings:

The acute toxicity studies submitted—MRID Nos. 488643-01, 487877-02, -04 and -06—are acceptable to support the reregistration of EPA Reg No. 43917-7.

The acute toxicity profile for EPA Reg. No. 43917-7 is currently:

Acute Oral	IV	Waived
Acute Dermal	IV	Acceptable
Acute Inhalation	IV	Waived
Primary Eye	IV	Acceptable
Primary Dermal	IV	Acceptable
Skin Sensitization	Non-sensitizer	Acceptable

NOTE: The acute toxicity requirements have been satisfied for the subject product.

Precautionary Labeling:

Product Reg. No.: 043917-00007

Product Name: Spira Area Mosquito Repellent

First Aid*:

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact [insert phone number 1-800-xxx-xxxx] for emergency medical treatment information.

*Note to Label Review Team: Due to the toxicity categories (Category IV), no **signal word** or **Hazards to Humans and Domestic Animals** statements are required. **First Aid** statements are optional. If the registrant wishes to include First Aid statements, they must be the same as those listed above.

DATA EVALUATION RECORD

Product Reg. No.: 43917-7

Product Name: Spira Area Mosquito Repellent

1. **DP BARCODE**: 409004

2. PC CODE: 004005

3. CURRENT DATE: June 17, 2013

Study/Species/Lab Study # /Date	MRID	Results	Tox Cat	Grade		
Acute dermal toxicity /rat Stillmeadow, Inc. Laboratory Study #: 14495-10 OCSPP 870.1200; OECD 402	487877-02	LD ₅₀ ♀+♂> 5050 mg/kg All animals (5 female and 5 male rabbits) survived. There were no clinical signs of toxicity or signs of dermal irritation at any time throughout the study. The gross necropsy revealed no observable abnormalities.	IV	A		
Primary eye irritation /rabbit Stillmeadow, Inc. Laboratory Study #: 14497-10 OCSPP 870.2400; OECD 405	487877-04	Non-irritating (based on 3 ♀ rabbits) There were no positive effects exhibited in any eyes after treatment.	IV	A		
Primary dermal irritation /rabbit Stillmeadow, Inc. Laboratory Study #: 14498-10 OCSPP 870.2500; OECD 404	488643-01	Non-irritating (based on 2 ♂ and 1♀ rabbits) Primary dermal irritation index = 0 All scores 0 at 72 hours	IV	A		
Dermal sensitization /guinea pigs Stillmeadow, Inc. Laboratory Study #: 14499-10 OCSPP 870.2600; OECD 406	487877-06	Negative Positive control α-Hexylcinnamaldehyde (HCA) appropriate (29 days).		A		

Grade Key: A =Acceptable, U = Unacceptable, D = Data Gap